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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,956

03/31/2004

Christine Meunier

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07/10/2008

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EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

07/10/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/812,956	Applicant(s) MEUNIER, CHRISTINE	
	Examiner BARBARA FRAZIER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 20, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 17-19, 21 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-11, 13-15, and 17-24 are pending in this application.
2. Claim 23 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/15/07.
3. Claims 20 and 22 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/15/07.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. The rejection of claim 17 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment to the claim.

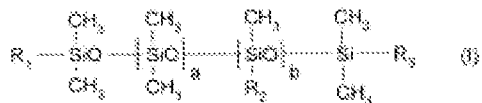
Claim Rejections - 35 USC § 103

6. Claims 1-11, 13-15, 17, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US Patent 6,007,799) in view of Lukenbach et al (US Patent 7,262,158).

The claimed invention is a composition according to claim 1:

1. (Currently Amended): A composition in the form of an emulsion comprising:

- (a) at least one aqueous phase dispersed in a fatty phase;
- (b) at least one glyceride of a C_6 to C_{22} fatty acid or of a mixture of C_6 to C_{22} fatty acids, which is polyoxyethylated and/or polyoxypropylated;
- (c) at least one C_2 - C_6 monohydric alcohol, wherein the monohydric alcohol is present in an amount of between 10% and 30% by weight relative to the total weight of the composition;
- (d) at least one silicone emulsifier of formula (I):



in which:

a is an integer of 0 to 400;

b is an integer of 0 to 30;

a and b cannot simultaneously be equal to 0;

R_1 , R_2 and R_3 independently represent a C_1 - C_6 alkyl radical or the radical $-(\text{CH}_2)_x-(\text{OCH}_2\text{CH}_2)_y-(\text{OCH}_2\text{CH}(\text{CH}_3)_2-\text{OR}_4$, at least one of the radicals R_1 , R_2 and R_3 being $-(\text{CH}_2)_x-(\text{OCH}_2\text{CH}_2)_y-(\text{OCH}_2\text{CH}(\text{CH}_3)_2-\text{OR}_4$.

R_4 represents a hydrogen atom, a C_1 - C_3 alkyl radical or a C_2 - C_4 seryl radical;

x is an integer ranging from 0 to 6;

y is an integer ranging from 1 to 30; and

z is an integer ranging from 0 to 30.

Applicants have elected the species comprising (b) PEG-6 caprylic/capric glyceride, (c) ethanol, and (d) the silicone emulsifier of formula (I) in the reply filed 8/15/07.

Lee et al teach a cosmetic composition in the form of a water-in-oil emulsion (i.e., an aqueous phase dispersed in a fatty phase; see abstract) comprising a silicone oil phase, preferably a cyclomethicone having 4 to 6 siloxane groups (col. 12, lines 11-14), ethanol (col. 11, line 11), and a silicone emulsifier containing dimethicone copolyol (col. 12, lines 37 – 41). The composition also includes a polar species that may be an ester derivative of a polyhydric alcohol (col. 11, lines 1-5). The composition may also have cosmetically active agents (col. 13, lines 25-27).

Lee et al do not specifically teach that the ester derivative of a polyhydric alcohol is PEG-6 caprylic/capric glyceride.

Lukenbach et al teach a cosmetic composition which may be a water-in-oil emulsion (col. 7, lines 34-35) having a water-dispersible component which, most preferably, is polyethylene glycol-6 caprylic/capric glyceride (col. 4, lines 9-10 and 21-24; also see Example 9, columns 26 and 27). The compositions of Lukenbach et al. may also have a silicone oil (col. 4, lines 5-6) and a silicone emulsifier, such as dimethicone copolyol (col. 14, line 55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select polyethylene glycol-6 caprylic/capric glyceride as taught by Lukenbach et al as the polyhydric alcohol ester derivative taught by Lee et al; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the selection of polyethylene glycol-6 caprylic/capric glyceride as the polyhydric alcohol ester derivative provides the composition with the benefits of reduced skin irritation, as well as the capability of depositing various active agents into and onto

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the skin, as taught by Lukenbach et al (see abstract and col. 1, lines 63-67).

Additionally, one skilled in the art would recognize that the addition of a known water-dispersible component such as PEG-6 caprylic/capric glyceride to a water-in-oil emulsion would be advantageous, since such an addition would allow the aqueous phase to disperse more easily in the fatty phase, and thus result in a more stabilized emulsion. One would reasonably expect success from the selection of polyethylene glycol-6 caprylic/capric glyceride taught by Lukenbach et al as the polyhydric alcohol ester derivative in the composition taught by Lee et al because both references are drawn to cosmetic compositions of water-in-oil emulsions having silicone oil and silicone emulsifier.

Regarding the amount of monoalcohol present (claims 1 and 24), Lee et al. teach that coupling agent (i.e., ethanol) is present in an amount of from about 10% to about 30% by weight (col. 11, lines 57-60); the amount is encompassed by Applicant's amount of 10-50% by weight (see claim 1).

Regarding the amount of silicone emulsifier (claim 6), Lee et al. disclose that the mixture of cyclomethicone and dimethicone copolyol is 4-20% by weight (col. 12, lines 49-52). Since the amount of dimethicone copolyol in DC 3225C (exemplified by Lee et al.) is 10% (as taught on page 8 of Applicant's specification), the amount of silicone emulsifier in Lee et al. would be 0.4-2% by weight relative to the total weight of the composition; this is encompassed by Applicant's amount, which is 0.1-5% by weight.

Regarding the presence of cyclomethicone (claims 7 and 8), Lee et al. disclose the composition has cyclomethicones of formula $((CH_3)_2SiO)_x$ where $x=4-6$; this is

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encompassed by Applicant's cyclomethicones of formula (III) having 3 to 8 siloxane groups (claim 7).

Regarding the amount of cyclomethicone (claim 9), Lee et al. state that the cyclomethicones are present up to 18%, preferably 4-12% by weight (col. 12, lines 9-12). This amount overlaps the amount of cyclomethicone in the claimed invention, and a person having ordinary skill in the art would be able to select the amount of cyclomethicone as a matter of routine optimization.

Regarding the ratio between silicone emulsifier and cyclomethicone (claims 10 and 11), Lee et al. cite the use of DC3225C, which has a silicone emulsifier/cyclomethicone/water ratio of 10/88/2, as cited in Applicant's claim 11.

Regarding the amount of fatty acid (claim 15), Lukenbach et al. disclose that the water-dispersible component is present in an amount of from about 10 percent to about 20 percent (col. 3, lines 60-61). This amount is comparable to the amounts claimed by Applicants (i.e., 0.1 – 10% by weight; see claim 15), especially given that the prior art uses the flexible modifier "about". In any case, it would have been obvious to determine workable and/or optimal amounts of pigment per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

Response to Applicant's Remarks

7. Applicant's arguments filed 3/17/08 have been fully considered but they are not persuasive.

Applicants first argue that the present invention relates to the discovery of a way to address stability problems suffered by emulsions containing a significant amount of monoalcohol and a glyceride by adding a specific type of silicone surfactant to the emulsion in an amount sufficient to improve the stability of the emulsion. Applicants then argue that the compositions of Lee already contain a significant amount of ethanol and a silicone surfactant. Applicants further argue that, given the stability problems associated with compositions containing a significant amount of monoalcohol and a glyceride of a C₆ to C₂₂ fatty acid or of a mixture of C₆ to C₂₂ fatty acids (as illustrated in Table 1 of the present application), no motivation whatsoever would have existed to add a glyceride of a C₆ to C₂₂ fatty acid or of a mixture of C₆ to C₂₂ fatty acids.

This argument is not persuasive. The data upon which Applicant relies, i.e., Table 1 of the present application, only teaches that there are stability problems with the combination of monoalcohol and fatty acid glyceride in the *absence* of a surfactant/emulsifier. As Applicants correctly point out, the composition of Lee already contains a monoalcohol and a silicone surfactant. Therefore, one skilled in the art would not be concerned about stability problems, since the surfactant/emulsifier is already present in the composition. Furthermore, Lee fairly suggests the presence of a polyhydric alcohol ester derivative (col. 11, lines 1-5).

Applicants argue that Lukenbach neither teaches nor suggests that polyethylene glycol-6 caprylic/capric glyceride would allow an aqueous phase to disperse more easily in a fatty phase and, thus, result in a more stabilized emulsion.

This argument is not persuasive because one skilled in the art would recognize that polyethylene glycol-6 caprylic/capric glyceride is water-soluble and dispersible in water, yet also has hydrophobic tendencies (by the presence of the fatty acid chains). Therefore, the compound improves the ability of the water to disperse in the fatty phase, and results in a more stabilized emulsion. The fact that Lukenbach teaches the presence of polymeric emulsifiers does not negate the fact that water-dispersible components, such as polyethylene glycol-6 caprylic/capric glyceride, are also taught.

Applicants argue that Lukenbach does not teach or suggest using polyethylene glycol-6 caprylic/capric glyceride as an emulsifying agent for any emulsion, let alone a particular type of emulsion having an aqueous phase dispersed in a fatty phase.

This argument is not persuasive because Lukenbach specifically teach that polyethylene glycol-6 caprylic/capric glyceride is present in a water-in-oil emulsion (see Example 9, columns 26 and 27).

Applicants finally argue that it is only through improper hindsight, using information from the present application, that one skilled in the art would have been motivated to add a C₆ to C₂₂ fatty acid or a mixture of C₆ to C₂₂ fatty acids to Lee's compositions with the expectation that a stable emulsion would result.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

8. Claims 18, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. and Lukenbach et al. as applied to claims 1-11, 13-15, 17, and 24 above, and further in view of Nadaud et al., US Patent 5,567,426.

Claims 18, 19, and 21 are drawn to the composition according to claim 1, further comprising at least one lipolytic active agent; Applicants have elected caffeine as the elected species.

The inventions of Lee et al. and Lukenbach et al. are delineated above (see paragraph 6). Lee et al. teach that the composition may be an emollient composition or a sunscreen composition (col. 8, lines 3-4), and can also have "additional cosmetically active ingredients" (col. 13, lines 25-27).

The invention of the combined references does not specifically teach that the "cosmetically active ingredient" may be caffeine.

Nadaud et al. teach cosmetic compositions in the form of emulsions comprising water, silicone oil and silicone emulsifier which are emollient compositions (col. 10, lines 51-58), or sunscreen agents (col. 11, lines 1-3), and where slimming products can also

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be obtained, having active substances such as caffeine (col. 11, lines 18-23). Thus, one skilled in the art would recognize that caffeine could also be an acceptable ingredient in the water/silicone emulsions of Lee et al., and if one desired formulating a slimming product one would have been motivated to select caffeine as the cosmetically active ingredient. The selection of a specific ingredient to perform the desired function is prima facie obvious.

Since all of the inventions are drawn to cosmetic compositions comprising water and silicone emulsions, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to select caffeine as the “additional cosmetically active ingredient” of Lee et al. in order to arrive at the claimed invention, with a reasonable expectation of success.

Regarding the amount of lipolytically active agent present (claim 21), Nadaud et al. disclose caffeine as being present at 0.4% by weight relative to the total weight of the composition (see Example 1, columns 11 and 12). This is encompassed by Applicant's amount of 0.1 to 10% by weight (claim 21).

Response to Applicant's Remarks

9. Applicants have not argued the merits of the instant rejection separately from the rejection of claims 1-11, 13-15, 17, and 24 over Lee et al (US Patent 6,007,799) in view of Lukenbach et al (US Patent 7,262,158). Accordingly, claims 18, 19, and 21 stand rejected for reasons stated above.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday - Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615